Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#

13009



7 - PROCEDURES

This copy for ==> Medical Records 02/03/98 discharge 01/28/98 admit

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Community of the program of the prog

Hematology

		Collection Date:	02/01/98	01/30/98	01/29/98	01/28/98	and the second s
		Collection Time:	0630	0355	0510	<u>1710</u>	•
Units:	Reference:			-	-		
		CBC					
x 10^3	4.8-10.8	wbc	/ *^^`` 8.5°	آهـ و آ	11.2H	_ 7.3	Section and management of the section of the sectio
x 10^6	4.20-5.40	rbc	3.86L	3.55L	3.68L	4.26	,
g/dl	12.0-16.0	hemoglobin	11.5 L	10.4L	10.8L	12.5	
8	37.0-47.0	hematocrit	33.9L	30.8L	32.1L	37.3	
uM3	80.0-100.0	mcv	87.7	86.8	87.3	87.5	to the second se
pg	27.0-31.0	mch	29.8	29.3	29.3	29.3	· ·
g/dl	33.0-37.0	mchc	34.0	33.8	33.6	33.5	
8	11.5-14.5	rdw	12.8	12.8	12.6	12.6	s Comments of Many Supplemental Comments of the Comments of th
x 10^3	140-440	platelets	225	183	203	240	, , , , , , , , , , , , , , , , , , , ,
x 10^3	.6-3.3	lymphocytes	2.2	2.1	2.6	3.1	
x 10^3	.1-1.1	monocytes	.7	.7	. 9	. 4	
x 10^3	2.0-7.5	granulocytes	5.6	7.0	7.8H	, 3.9	· spenier of the second of the
		Manual Differential	Active or all Allians 200.	5-00 00/324 11.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
%	20-70	segs			66		
8	0-10	bands			1		
8	6-33	lymphs			21		
- %	0-11	monos	or I amplifications	20030000 12 18,826, 24 11 7	10	•••	
8	1-3	eos		•	2		
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 	Normal .	RBC Morphology	- مىرىن د	: - · · · · · · · · · · · · · · · · · ·	Normal		A management

Chemistry

Profiles

Collection Date: 01/30/98 01/29/98 01/28/98 0510 1710 Collection Time: 0355

Units:	Reference:	San 2000 - And the		C & D			and Planeding Co
		Fasting?	FASTING	UNKNOWN	UNKNOWN		
,		Fasting?			UNKNOWN		
MG/DL	70-110	Glucose	109	114 H	122 H		
MG/DL	70-110	Glucose		*******	122 H	,	and a second and a second
MG/DL	7-18	BUN	5L	11	14		
MG/DL	7-18	BUN			14		
MG/DL	0.6-1.0	Creatinine			0.8		
MMOL/L	136-146	Sodium	138		140	- January	
MEQ/L	3.6-5.2	Potassium	3.7	4.1	3.9	* * *	The state of the s
MOL/L	98-106	Chloride	107 H	108 H	105		
MMOL/L	22-29	CO2	23	22	24		
G/DL	6.4-8.2	Total Protein	ere amagazar aras	Jeens or supplied to the state of the state	6.7	,	1 15 water many water 2 date monday
G/DL	3.2-5.1	Albumin			``````````````````````````````````````	2 Maria (
MG/DL	8.8-10.5	Calcium	_	, ,	8.9		
- MG/DL	2.5-4.9	Phosphorus	_	•	2.3L		
MG/DL		Total Bilirubin	· · · · · · · · · · · · · · · · · · ·	and the constant and all the constants and the constants and the constants are constants and the constants and the constants are constant are constants ar			· · · · · · · · · · · · · · · · · · ·
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FASTING	UNKNOWN	UNKNOWN		
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	57747	122 H	,u(11 *	
5L	11	14		
		14		
		0.8		
138	139	140		
138 3.7	4.1	3.9		
107 H	108 H	105		
23	22	24		
	pecaries supplies 25	6.7	,	
,	and and a second and and a	3.8	e established to	``
	,	8.9		
	•	2.3L		

L = Low, H = High

bold= abnormal

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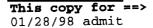
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Chemistry

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		Collection Time:	01/30/30	0510	1710				
	Reference:	Collection lime:	, , , , , , , , , , , , , , , , , , ,	**************************************		ingresser (100 gradus	~~~~ <u>~~~~~</u>		.535 -
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MG/DL MG/DL	0-200	Cholesterol			154			***	
	20-160	Triglycerides			91				
MG/DL	20-160 50-136	Alk Phos		· · · · · ·	100		www.common	occupation to the second secon	
U/L	15-37	SGOT	•	ي ي	18		×9		
U/L		LDH			116			1 14 T	
IU/L	80-220	EDH			110				
		Serum Analytes	× ×	ga 11 1111	. ** ***	S->-: S->	v +4+>>,,59,5,400,7000,99	a section in the section of the sect	2 15
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		Collection Date:	02/03/98	02/02/98	02/01/98	01/31/98	01/30/98	01/30/98	
		Collection Time:	0540	0524	0630	0500	1500	0355	
Units:	Reference:	Collection lime.							
MG/DL	0.6-1.0	Creatinine						0.6	
	1.8-2.4	Magnesium	2.0	1.8	1.8	1.7L	2.1	1.5L	
MEG/L	1.8-2.4	Magnesium	2.0						
		Collection Date:	01/29/98	01/28/98	:	55\			Mere C 2000
		Collection Time:	0510	1710		*		· Shirten was a contra	
Units:	Reference:	COTTECCTOR TIME.			-				
MG/DL	0.6-1.0.	Creatinine	0.7		_				
MEG/L	1.8-2.4	Magnesium	1.6L	1.5L	"))) ຳ ຄູເ ເ · · · · ·	20058741,001-2574588-2010/00/00	S. C. L. S. C.	To the state of th	**
MEG/D	1.0-2.4	130911001001		-	•			and an analysis of the same of	
		Cardiac Enzymes							
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		Collection Date:		01/29/98				· / Life takunda sa arorus	
		Collection Time:	<u> 1730</u>	0015	<u> 1710</u>	_			
Units:	Reference:								
U/L	21-215	Random CPK			,	*** * * * * * * *		ersentifikat (DC)	
U/L	21-215	CPK 8hr		305H				an Baratil	
NG/ML	.0-5.0	CKMB 8hr						8-	
8	0.0-3.0	CKMB Calc 8hr		12.3 H					
U/L	21-215	CPK 24hr	164 _	arr a se in incorrer in inco	وسديد ين	الرياقهو ۱۳۵۰ د استسام	oma angerin	Taria de la Caración	T
NG/ML	.0-5.0	CKMB 24hr	13.9H		,			"Cartherto Andrita in a de el companio de el co	
14(2) 1111									
U/L U/L NG/ML % U/L	21-215 21-215 .0-5.0 0.0-3.0 21-215	CPK 8hr CKMB 8hr CKMB Calc 8hr CPK 24hr	., . 8" ^, "	37.5H 12.3H		semine i stoprigelije			

Legend

L = Low, H = Highbold= abnormal.

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printed 02/04/98 0421

01/28/98 admit

This copy for ==> Medical Records

02/03/98 discharge

p. 3

Toxicology

Collection Date: 01/28/98 Collection Time: 2130

Units: Reference:

1.005-1.035 U,Spec Gravity: 1.017 NEGATIVE " U, Alcohol negative POSITIVE* U, Amphetamines NEGATIVE

NEGATIVE U,Barbiturates NEGATIVE NEGATIVE NEGATIVE U, Benzodiazepin NEGATIVE NEGATIVE U,Cocaine NEGATIVE U,Opiates NEGATIVE NEGATIVE U, Tetrahydrocan NEGATIVE

Coagulation

Collection Date: 02/01/98 01/30/98 01/29/98 01/28/98

- 3 .

Collection Time: 0630 0355 0015 1710

Units: Reference: 12.1 Protime 11.0-14.0 sec 1.02f INR 24 >120f >120f 23 PTT 3.0 <

CALLED TO UNIT TO 01/30/98 04:50. 01/30/98 0355 PTT

___ 01/29/98 0015 PTT

REPEATED & CONFIRMED PTT. CALLED TO

.01/29/98 00:57

(04/27/95 -- Current) ANTICOAGULANT RANGE: MODERATE INTENSITY 2.0-3.0 HIGH INTENSITY 2.5-3.5

Urinalysis

Collection Date: 01/29/98 01/28/98 Collection Time: 1940 2130

Units: Reference:

Dipstick negative negative Glucose negative Bilirubin negative negative negative negative negative Ketones negative 1.010 >=1.030 <=1.035 SpecificGravity negative negative negative Blood 6.0 6.0 4.5-9.0 pН negative 30 mg/dl* negative Protein 0.2 E.U. 0.2 E.U. <=1.0E.U Urobilinogen negative negative Nitrate negative negative trace* Leuk Esterase negative

Legend

f = Footnote

bold = abnormal

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printed 02/04/98 0421

01/28/98 admit

This copy for ==> Medical Records

02/03/98 discharge

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Urinalysis

Collection Date: 01/29/98 01/28/98 Collection Time: <u>1940</u> 2130

Units: Reference:

Microscopic

Urine Character sl hazy* clear yellow Urine Color 0-2/hpf* WBC/HPF 0-2/hpfnegative RBC/HPF 0-2/hpf1+* Squamous Epith Renal Epith negative 1+* negative Bacteria negative negative Amorphous

negative Crystals rare* negative Mucus negative Hyaline Cast 0-2/lpf

Blood Bank Cumulative Summary

- 7.

Collection Date: 01/29/98 1730 Collection Time:

Blood Group and Type

O POS ABO Rh type

Antibody Screen and Identification

Antibody Screen negative

Ordered Procedures that are Pending

Drawn Date/Time Status Test Pending 02/02/98 0524 MISC 02/02/98 0524 Pending MISC 01/28/98 2211 Pending UA

bold= abnormal

end of report

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FINAL

- 5

38 YRS 02/02/98

ACC# 河岸排: RM#: DR.

DATE COLLECTED: 02/02/98

FIME LOLLECTED: 0524

HOMOCYSTEINE, TOTAL PLASMA

REFERENCE RANGE 3-14 UMUL/

THE RISK FOR CORONARY VASCULAR DISEASE INCREASES PROGRESSIVELY WITH HOMOCYST(E) INE COMCENTRATIONS ABOVE 9 UMOL/L. FOR EXAMPLE. A 3.4 TIMES GREATER RISK IS ASSOCIATED WITH A CONCENTRATION /15.5 UMOL/L AS COMPARED TO (14.1 UMOL/L.

SEE JAMA, 268; NO. 7, P.879,1992.

Uniess noted, all test(s) performed at

DATE PRINTED: 02/05/98

Page 1

END OF REPOR

DEPARTMENT OF IMAGING

PATIENT NAME:

MR#: MD

DOB:

DATE OF EXAM:

01/28/98 SEQUENCE #:

INDICATION:

CHEST PAIN

CHEST PORTABLE:

The heart is of normal size and contour. The mediastinum, hilar structures and pulmonary vascularity are within normal limits. The lungs are well expanded and clear and the costophrenic angles are acute. The bony structures are unremarkable.

IMPRESSION:

Negative study of the chest.

Dictated by:

DO

Released by:

01/29/98 10:08

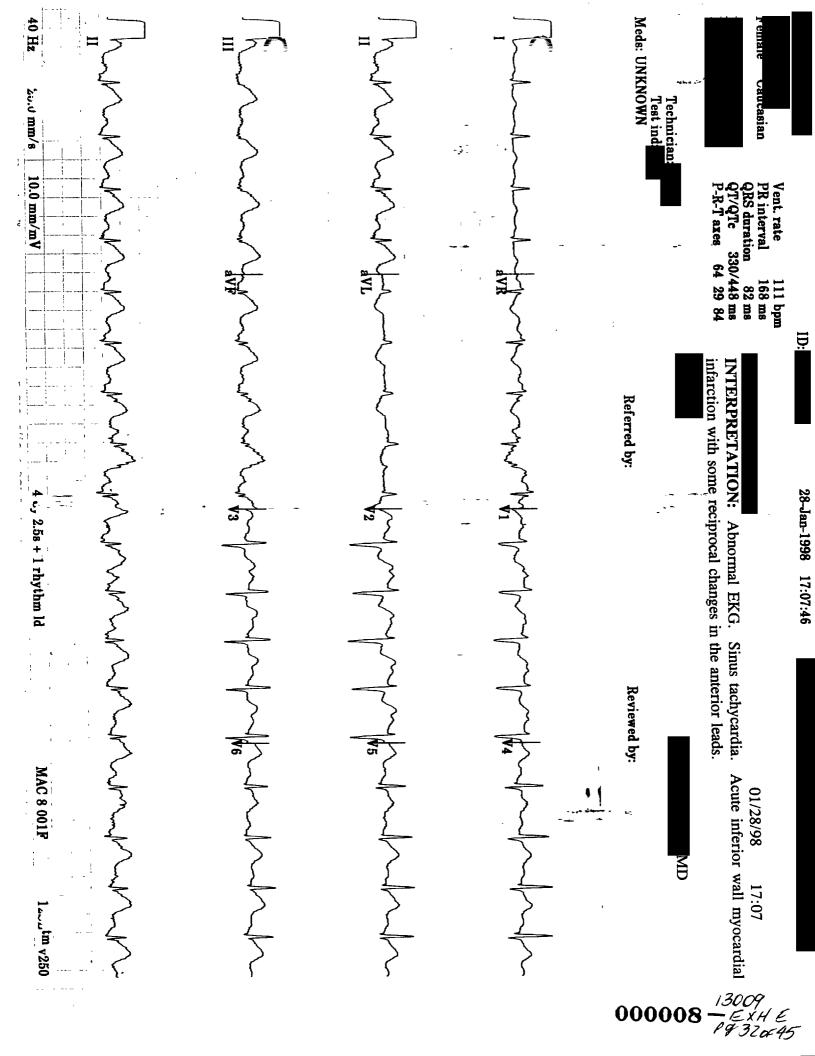
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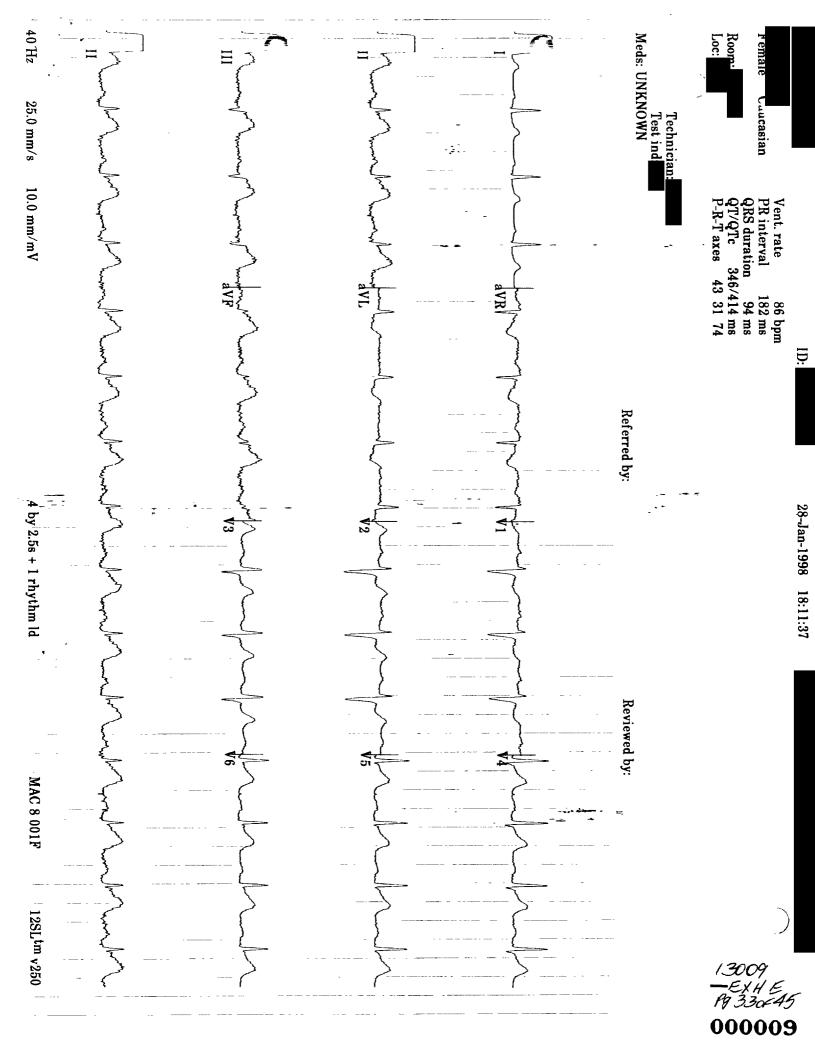
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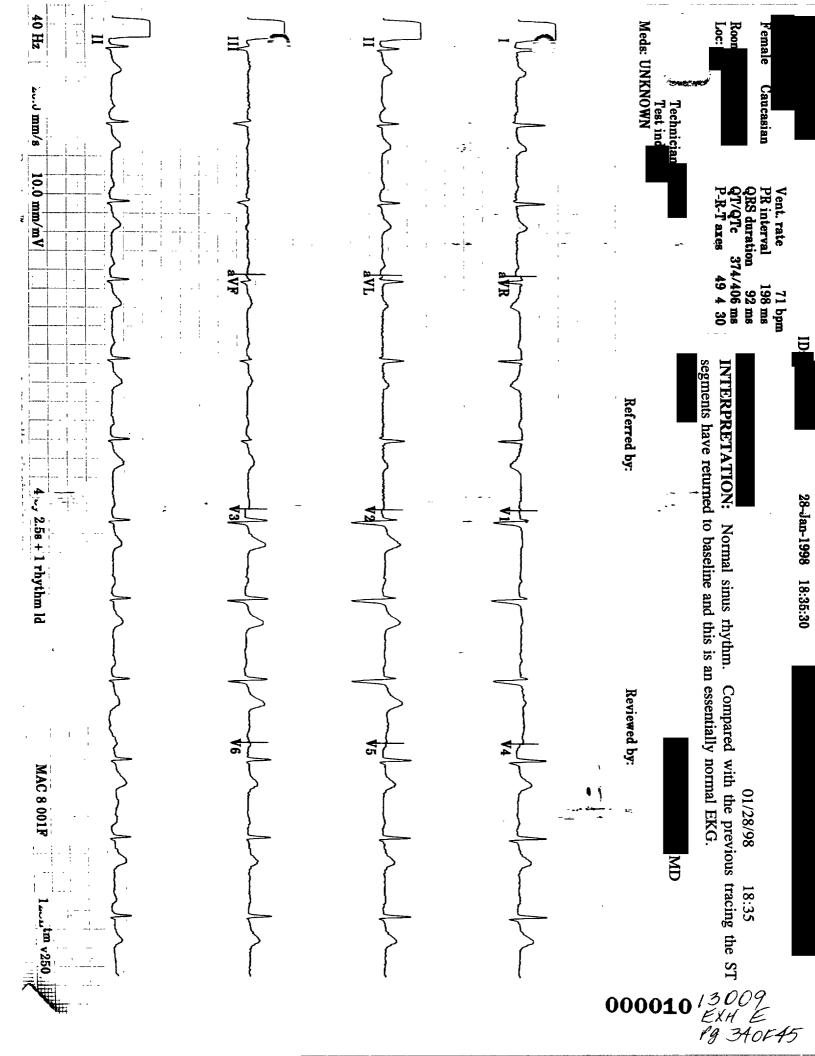
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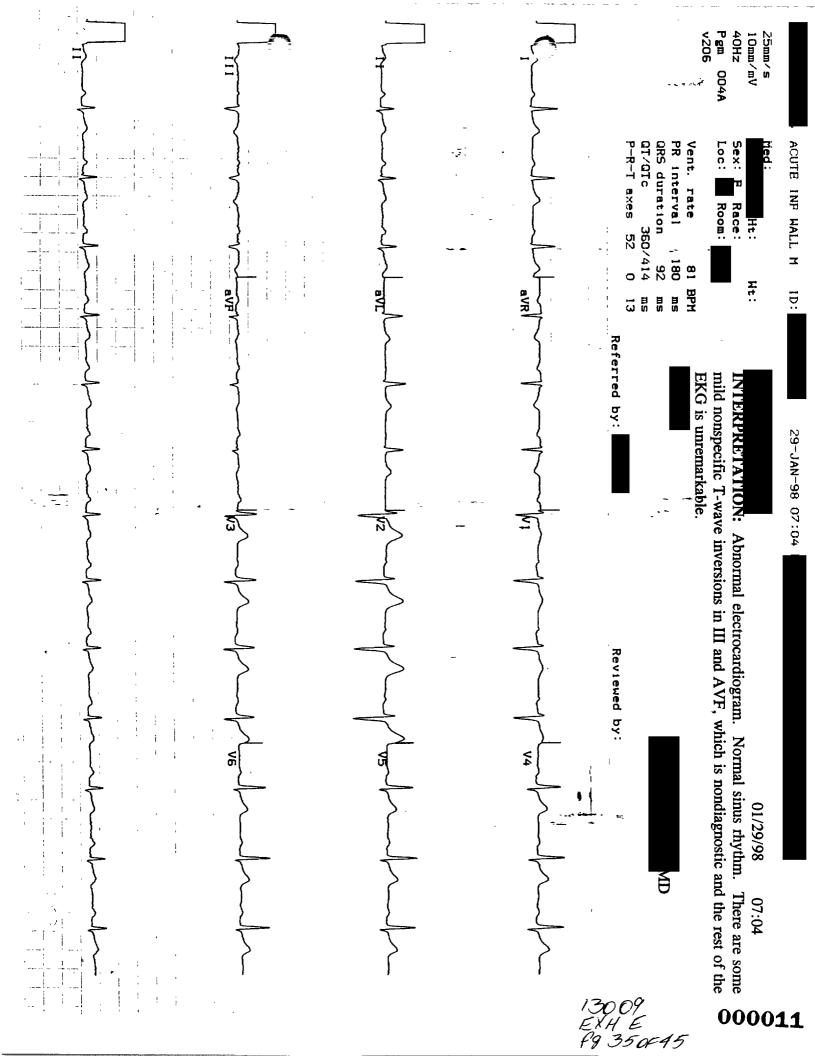
X-ray file copy

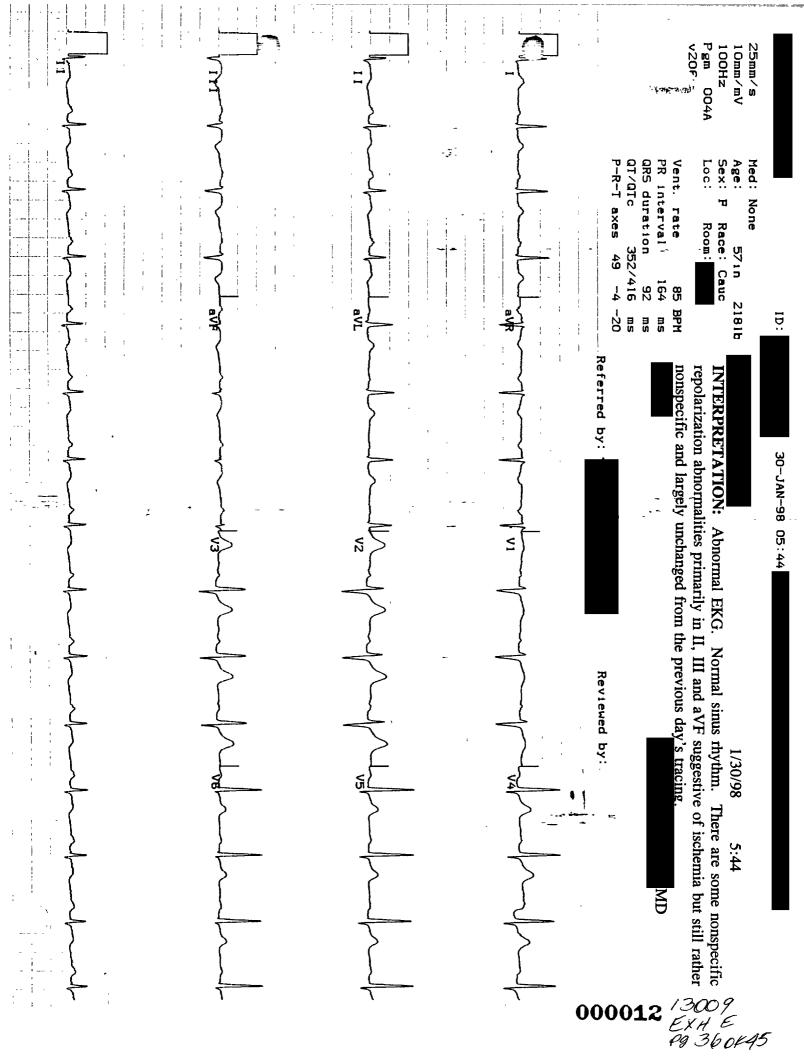
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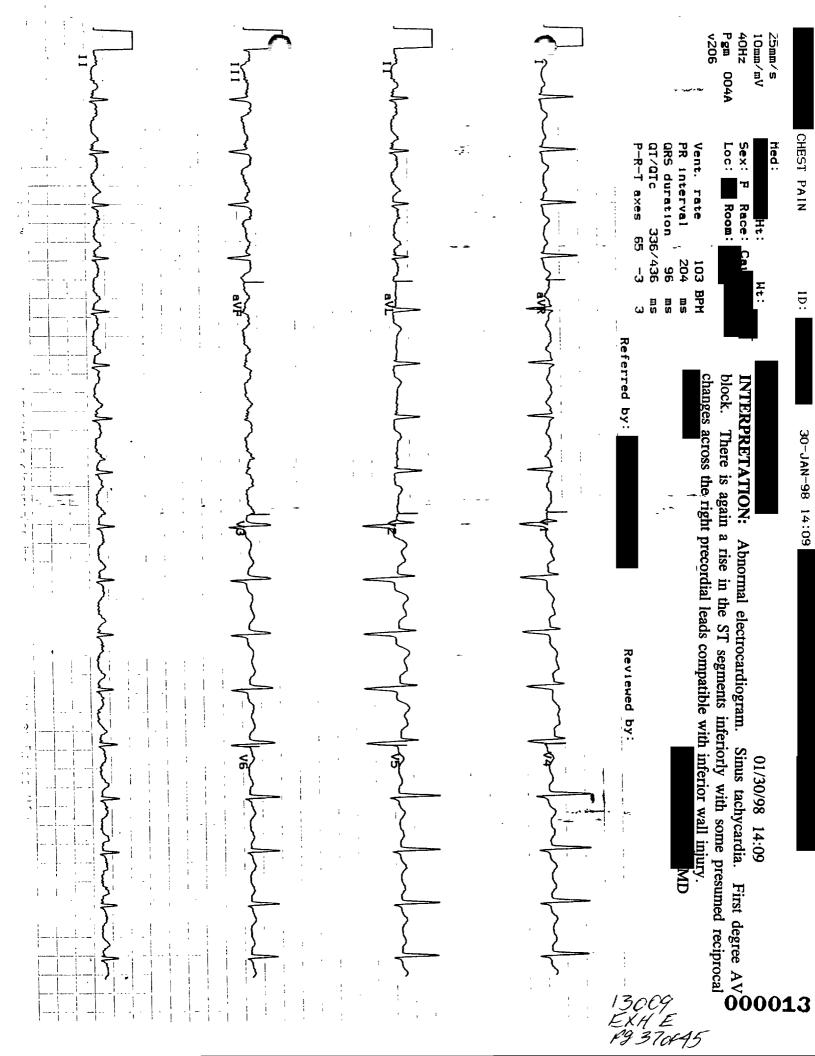


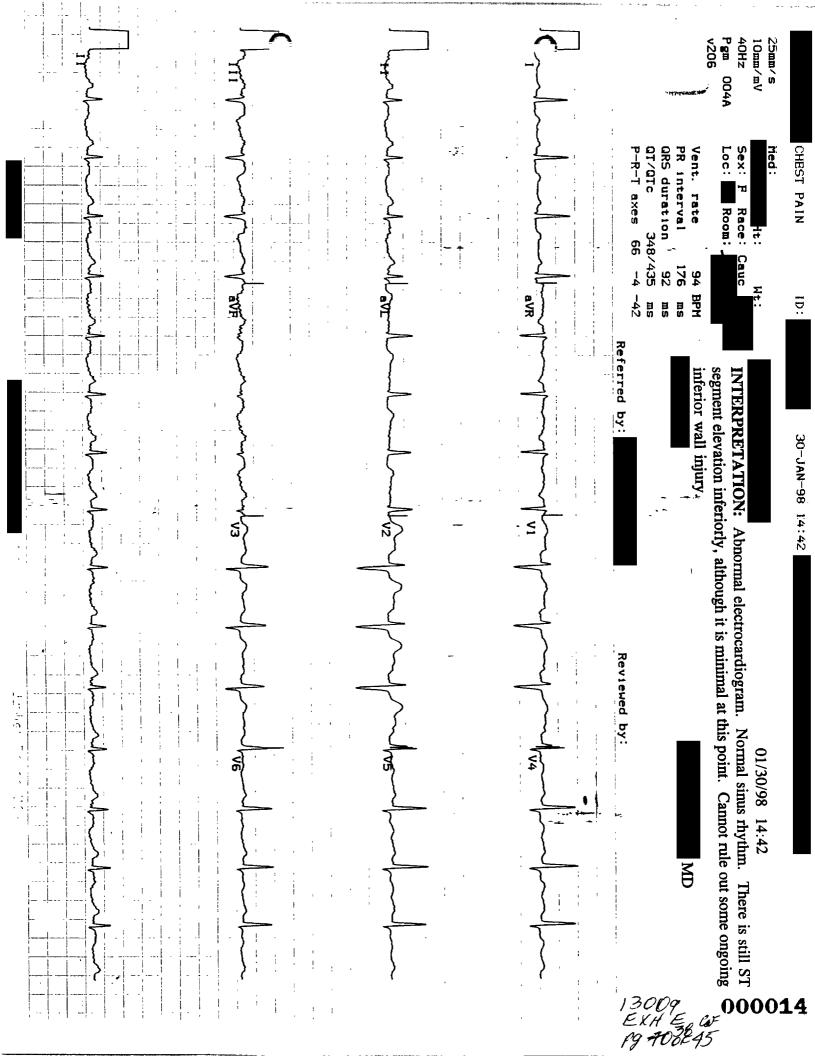


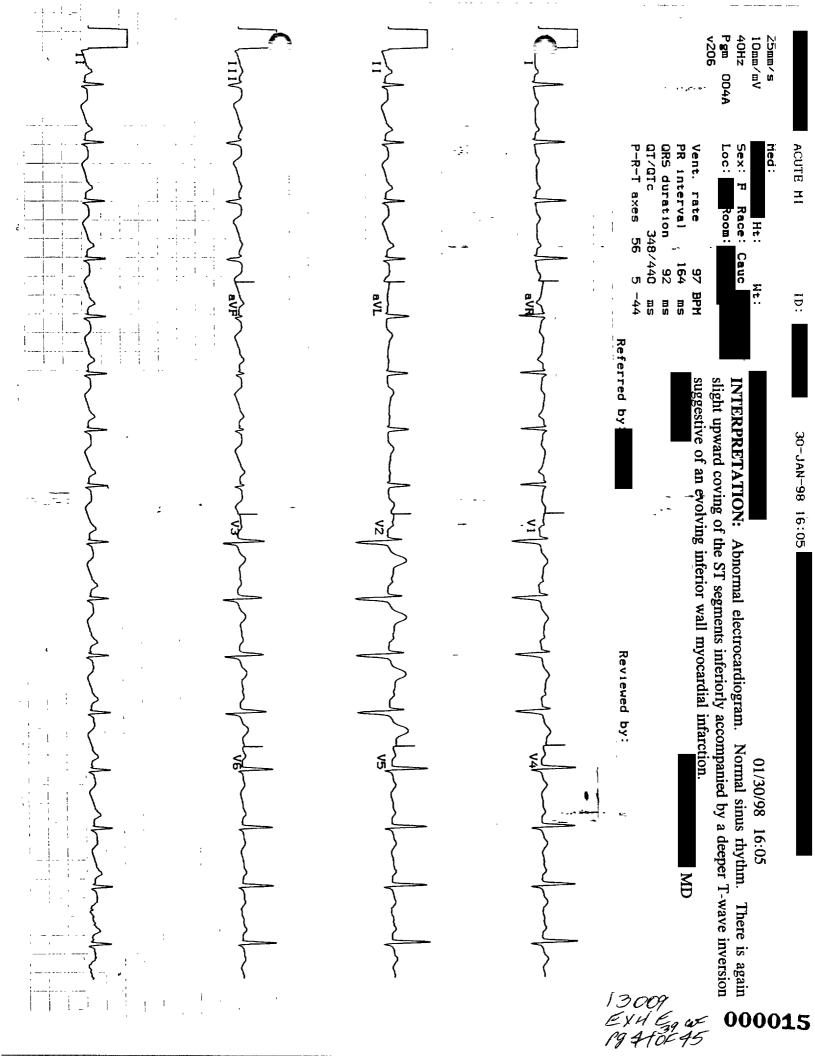


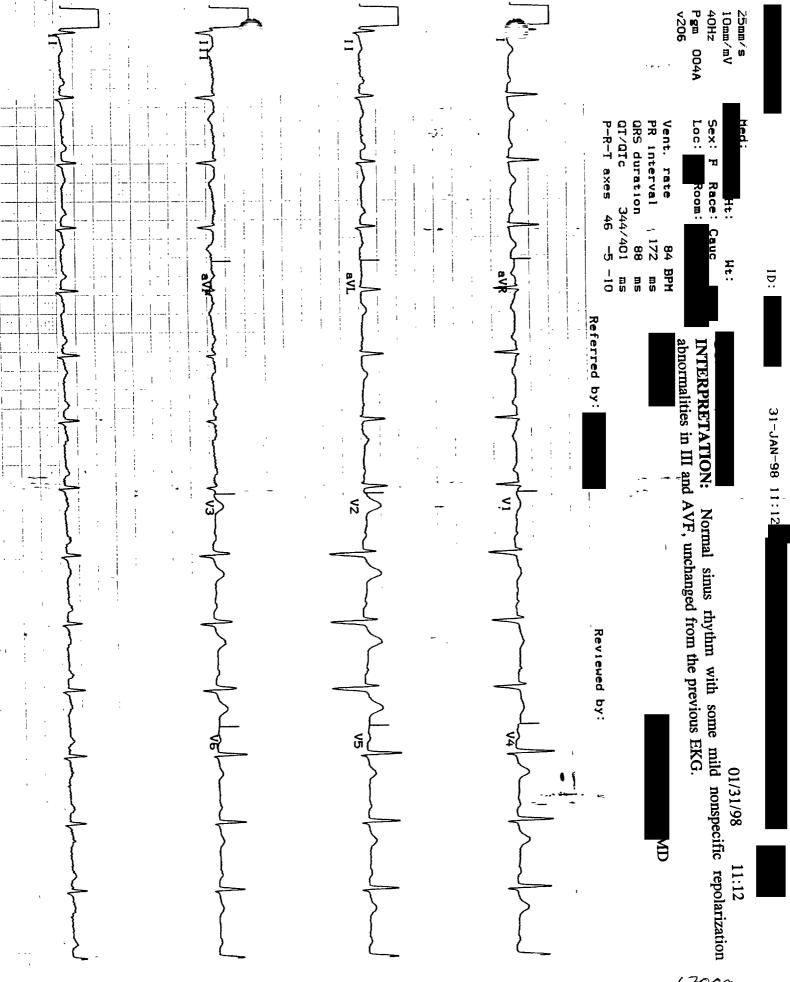




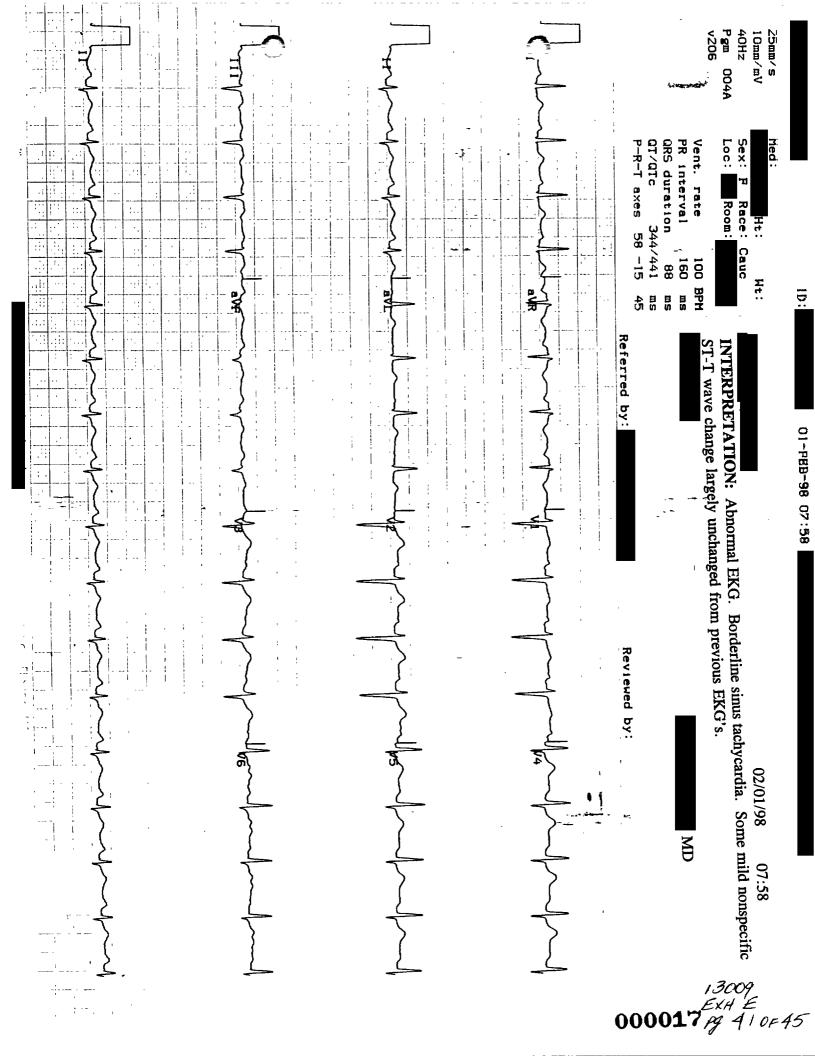








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OPERATIVE REPORT

MR#:

ACCT#

PATIENT NAME:

01/28/98

DATE OF ADMISSION: 01/30/98 DATE OF SURGERY:

ADMITTING PHYSICIAN: REFERRING PHYSICIAN:

SURGEON:

MD MD

PREOPERATIVE DIAGNOSIS:

Coronary artery disease

POSTOPERATIVE DIAGNOSIS:

Same

Left heart catheterization, selective cine coronary TITLE OF OPERATION: arteriography, left ventriculography

INDICATIONS: Mrs. is a 38 year old white female who was admitted to the hospital with an acute inferior myocardial infarction. It appeared to Thave been aborted with the use of intravenous heparin and nitroglycerin, and eteplase. Because of the young age and the aborted nature of her infarct, it was elected to proceed on with coronary angiography.

The patient's right femoral area was prepped and draped in the usual manner. Under 1% Xylocaine anesthesia, a percutaneous puncture of the right femoral artery was made using the Seldinger technique. A 7 French vascular sheath was placed within the right femoral artery. Through the indwelling arterial sheath a 7 French pigtail catheter was inserted and with the use of the J tip guide wire positioned in the ascending aorta. Pressures were obtained using the Statham P-23 DBI pressure transducer and a Mennen Medical Physiologic Recorder. The catheter was advanced across the aortic valve and pressures were repeated within the left ventricle. At this point the pigtail catheter was connected to a power injector and left ventriculograms performed in the RAO and LAO views. The pigtail catheter was reconnected to the pressure transducer and pressures were again repeated within the left ventricle and a continuous pullback pressure across the aortic valve was recorded. At this point the pigtail catheter was removed and exchanged for a 7 French 4 cm Judkins left coronary catheter which, with the use of the J tip guide wire, was positioned in the ascending aorta. The catheter was advanced to the ostia of the left coronary artery and multiple hand injections of dye were The left coronary catheter was then performed in a various positions. removed and replaced with a 7 French 4 cm Judkins right coronary catheter which, with the use of the J tip guide wire, was positioned in the ascending The catheter was advanced to the ostia of the right coronary artery and multiple hand injections of dye were performed in various positions. right coronary catheter was then removed. The femoral sheath was removed. Vasoseal was used for hemostasis. The patient tolerated the procedure well





13009 EXHE Pg 160+15

OPERATIVE REPORT

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PATIENT NAME:

MR#: ACCT#:

and there were no complications. At the end of the procedure the patient had excellent dorsalis pedis and posterior tibial pulses.

MD

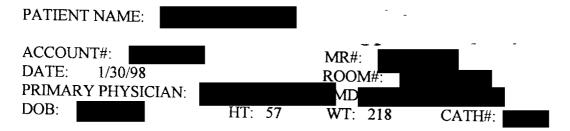
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D:

cc: MD

13009 EXH E Pg 170=45

CARDIAC CATHETERIZATION SUMMARY



- ====

ago while at work she noticed sudden onset of severe chest discomfort associated with dyspnea, diaphoresis, and nausea. She was brought immediately to the Emergency Room at where an electrocardiogram was compatible with extensive inferolateral myocardial infarction. She was given intravenous Heparin, intravenous Nitroglycerin, and thrombolytic therapy in the form of Reteplase within 2 hours of the onset of her chest pain. Within 4 hours of the onset of her chest pain, her pain had subsided and her electrocardiogram had returned to normal. There was minimal CPK elevation. Because of her young age, female status, and what appears to be an aborted inferior infarct, cardiac catheterization was recommended. Prior to this episode of chest pain, there has been no prior history of any significant angina. There has been no known prior history of hypertension, diabetes or abnormal lipids. The patient is a nonsmoker. There is no family members with a history of coronary disease.

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PHYSICAL EXAMINATION: Physical exam reveals a healthy white female in no distress. Blood pressure 136/80 mm of mercury. Pulse 72 beats per minute and regular. Neck veins are not distended. Both carotids show normal upstroke without evidence-of bruits. Thyroid is not palpable. Chest is clear. Auscultation of the heart revealed the first and second sounds to be normal. There are no murmurs, gallops, or rubs appreciated. Examination of the abdomen is unremarkable. All pulses are palpable. There is no evidence of edema.

PRIOR DIAGNOSTIC STUDIES: Electrocardiogram on admission shows ST segment elevation in leads II, III, AVF and V4 through V6 with ST segment depression in V1 and V2. With pain relief, her electrocardiogram returned to normal. Peak CPK was 305. Chest x-ray is normal.

PURPOSE AND METHODS: The cardiac catheterization is undertaken in Mrs. to visualize her underlying coronary anatomy in view of her young age and recent aborted inferior infarct.

Left heart catheterization was undertaken via percutaneous puncture of the right femoral artery using the Seldinger technique. A 7 French pigtail catheter was used to record the left heart pressures using a



13009 EXH E Pg 18 OF 45

CARDIAC CATHETERIZATION SUMMARY

NAME:

- = :

DATE: 1/30/98

Statham P 23 DBI pressure transducer and a Mennon medical physiologic recorder. Pigtail catheter was likewise used in conjunction with the power injector to perform left ventriculograms in the RAO and LAO views. Judkins preformed right and left coronary catheters were used for the selective Cine coronary arteriograms utilizing hand injections of dye. All dye injections were made using Isovue contrast material and the selective Cine coronary arteriograms were recorded using digital angiography recorded on a computer disc.

- ,

ANGIOGRAPHIC RESULTS: Please refer to the photographs which were printed from the computer disc.

A-B: Right coronary artery, LAO cranial caudal view, proximal and distal segments respectively.

C: Right coronary artery, PA cranial caudal view.

D-E: Right coronary artery, RAO projection, proximal and distal segments respectively. The right coronary artery is a super dominant vessel. It has smooth walls throughout its entire course with no significant narrowing noted. The posterior descending coronary artery appears extremely small and appears to be amputated as designated by the arrows in B and C. This has the appearance of a totally obstructed posterior descending coronary artery. The remainder of the right coronary artery as noted shows no residual narrowing.

F-G: Left coronary artery, RAO projection, end diastole and end systolic respectively.

H-I: Left coronary artery, RAO caudal cranial views, proximal and distal segments respectively.

J-K: Left coronary artery, LAO projection, proximal and distal segments respectively.

L: Left coronary artery, hemi-axial view.

M: Left coronary artery, PA caudal cranial view. There is an area of 70% narrowing in the intermediate coronary artery as designated by the arrow in H, L, and M. The remainder of the course of the left coronary artery is free of significant coronary atherosclerosis.



13009 EXHE Pg 190F45

CARDIAC CATHETERIZATION-SUMMARY

NAME:

DATE:

1/30/98

N-O:

Left ventriculogram, RAO projection, end-diastole and end-systole respectively.

- <u>.</u> . .

P-Q:

Left ventriculogram, LAO projection, end-diastole and end-systole respectively. There is a small area in the mid portion of the inferior wall that is hypokinetic as outlined by the dots in O. The remainder of the left ventricle contracts normally and vigorously. Estimated left ventricular ejection fraction is .55. There is no evidence of mitral

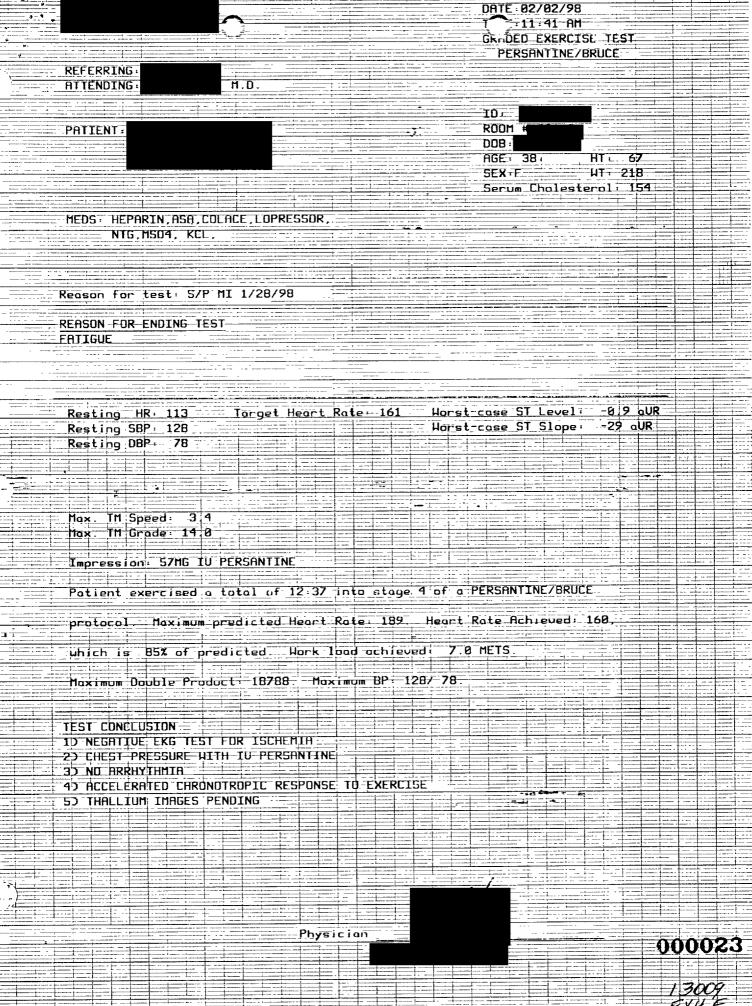
regurgitation.

HEMODYNAMIC RESULTS: Please refer to the pressures listed on the attached sheath which were obtained at the time of left heart catheterization. As can be seen, they are slightly elevated. This is in keeping with the left ventricular dysfunction noted at the time of ventriculography as well as the use of the beta blocking agent.

DIAGNOSIS:

- 1. Arteriosclerotic cardiovascular disease, 70% narrowing mid portion of the intermediate coronary artery, probable total obstruction of the posterior descending coronary artery, presumed right coronary artery spasm.
- 2. Mid inferior wall hypokinetic area.
- 3. Mildly elevated left heart pressures.
- 4. These studies rule out significant aortic stenosis, subaortic obstruction or mitral regurgitation.

RECOMMENDATIONS: has evidence of routine atherosclerotic coronary artery Mrs. disease with a lesion in her intermediate coronary artery. The posterior descending branch of her right coronary artery appears to have been totally obstructed. The electrocardiographic changes on her admission to the hospital, however, would suggest that the right coronary artery was totally involved at the time of her presentation. The remainder of the right coronary artery at the present time has no significant residual lesion suggesting that there may be an element of superimposed spasm as well. Mrs. was given the option of proceeding on to balloon angioplasty to the intermediate coronary artery or since she will have to remain on longacting nitrates and calcium blocking agents for presumed right coronary spasm whether to treat medically and use a thallium exercise test as an indicator whether to intervene in the intermediate coronary lesion or not. She chose the latter approach. would suggest that she be placed on 2 baby aspirin a day, longacting Nitroglycerin, longacting calcium blocking agents, and be followed closely clinically to detect any evidence of recurrent right coronary spasm. A follow up intravenous Persantine thallium stress test will be undertaken to ascertain whether



PG 13 OF 4

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Pa	tient:						Dat	e: 02/0	2/98	
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<u>L</u> 00	<u>cation</u> .			·						
Pro	otocol PE	RSANTIN	NE/BRUCE			===:	Lev	el J+	60	
	tending:		MD.				 51o	pe J+	20 to 8	8
Re ⁻	ferring:					· · · · · ·				
		••				~ 4	-			
_ EUENT	TIMES	SPEED -	GRADE	HR	BP	U0 ₂	HR X BP S	T LEUEL	ST_LEUEL	ST LEUEL -
	======((%)	Cbpm)	Cmm Hg)			Cmm)	Cmm)	Cmm)
								II	V5:	WORST
REST	SUPINE			— 98·	-1:28/- 78			-0.7	0.2	-0.4 aUR
	SUPINE-			113 .	128/ 78	97 0 - ·-	14464	07	0.1	-0.4 aUR
C+ 1	D1 . 25	8 0	a a	112	/	97 0	9	0.6	я я	-0.3 aUR
Stage 1	01 : 35 03 : 05	0.0 0.0	9.0	113 119	122/ 68	97.0	14518	0.5	9.8	-0.3 aUL
	9 4 : 36				122/-78		16836	0-5	-0.1	-0.4 U4
	06 : 05		0.0		110/72	970	17380	8.9	9.4	-0.5 aUL
	<u>86÷37</u>	THALL	IUM INJE	CTED			<u> </u>			
Stage 2	01:38	1.7	10.8	156	-==/	— 97 Я	0	1.0	9.5	-Ø.5 aUL
	03-00	1 . 7-	- 100	157			17270		9.6	
			-							
- Stage 3	01 ; 38		12.0_	159	/	97.70	0	1 3	. Ø.5	
	03.00	2.5	12.0	160	104/ 50	97.0	16640	1.2	0.6	-0.7 aUR
Stage 4	90 00	2.5	12.0	160		97 . 0		1-2	0.6	-0.7 aUR
	rcise e12									
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recovery	01:38	0.0	. 0.0 0.0	147	1187 56	27. ≀0 97. R	15620			-0.7 QUL
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NUCLEAR CARDIOLOGY -

PATIENT NAME: MR#:

MID

DOB:

MD

DATE OF EXAM: 02/02/9

SEQUENCE #: SPECT IV PERSANTINE THALLIUM:

EXERCISE DATA: The patient was administered 57 mg of Persantine IV over a 4 minute period. She was then ambulated on a treadmill, on a Bruce protocol, achieving a peak heart rate of 160 beats per minute and a peak blood pressure 128/78. The patient had no chest pain. She did have some slight chest pressure with IV Persantine.

At peak exercise, the patient was administered approximately 3 mCi of thallous chloride. She was then imaged using the standard SPECT imaging

techniques.

Thallium images reveal the quality to be good although the redistribution images are slightly mottled. There is a mild decrease in counts involving the basal portion of the inferior wall. This does not appear to change from stress to redistribution. The remainder of the myocardium appears to be well perfused. I see no evidence of Persantine or exercise induced ischemia.

IMPRESSION:

- Mild chest pressure with Persantine.
- No ischemic EKG changes.
- 3. Thallium images revealing a previous infarct of the basal inferior wall. I see no evidence of Persantine or stress induced ischemia.



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